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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/183,375	10/30/1998	JANOS SZEBENI	003/098/SAP	3056

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/183,375

Applicant(s)

SZEBENI ET AL.

Examiner

Gollamudi S Kishore, PhD

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 11, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 14, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The filing under 1.114 dated 6-18-03 is acknowledged.

Claims included in the prosecution are 1-6, 10, 14 and 16-17. Claims 7-9, 11, 18 and 19 remain withdrawn as directed to non-elected invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 10, 14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharriere (5,744,156).

Ko discloses a method of inhibiting complement activation by administering complement activation inhibitors. The method involves the administration of the inhibitor in controlled release delivery devices such as liposomes. The method is used for various conditions including the drug induced allergies and inflammation (note the abstract, col. 3, lines 49-52, col. 5, lines 32-51, col. 11, lines 1-42, examples and claims). Although Ko does not specifically teach the administration of the inhibitor together with the drug, it would have been obvious to one of ordinary skill in the art to administer together since Ko is suggestive of this combination from his statements on col. 10, line 42 et seq., according to which the inhibitor "can be combined with appropriate pharmaceutical formulation. An artisan would be motivated further to

administer the drug or an agent, which causes the side effects along with the inhibitor since the reference of De Lacharriere teaches such a concept; according to De Lacharriere hydroxy acids which cause side effects and the substance P antagonist which prevent these side effects are administered together. The criticality of cremophor (an amphiphilic compound) is unclear in the absence of unexpected results.

Applicant's arguments including those filed with the EPO have been fully considered, but are not found to be persuasive. Applicant argues that Ko teaches chimeric molecules which inhibit complement activation and these proteins are taught to reduce the inflammation and that the conditions mentioned include those associated with ischemia-reperfusion, crash injury etc., and the table I referred to by the examiner are targets to try. This argument is not found to be persuasive since Ko is suggestive of the efficacy of the complementation activation inhibitor and one skilled in the art would be motivated to use these with a reasonable expectation of success. Applicant argues that none in the table is an immediate complement reaction like that disclosed here in. This argument is not found to be persuasive since as applicant himself admits that Table does mention drug allergy. It would have been obvious to one of ordinary skill in the art that this expression means it is immediate (allergic reactions show up reasonably quickly) and that the complement activation inhibitor would act against the allergy whether the compounds, which cause the hypersensitivity, are classified as drugs or not since the inhibitor treats the symptoms. There is nothing in Ko, which indicates that the drug hypersensitivity reaction is not an immediate reaction. With regard to applicant's arguments that De Lacharriere does not teach hypersensitivity associated with complement activation by amphiphilic molecules, the examiner points out that De Lacharriere is combined to show that administration of compositions causing side effects together with those which reduce the side effects is routinely practiced in the art.

3. Claims 1-6, 10, 14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharriere (5,744,156), in further combination with applicant's statements of prior art.

Neither Ko nor De Lacharriere teaches the use of cremophor as a drug or as a carrier. The references do not also teach that cremophors or liposomes cause compliment activation. Applicant on pages 5 and 6 cite various references, which show that cremophors and liposomes cause compliment activation. Since the reference of Ko teaches that the inhibitors of complement activation for the treatment of conditions resulting from complement activation, it would have been obvious to one of ordinary skill in the art to use Kook's inhibitors for cremophor induced side effects since one would expect similar results irrespective of what causes the complement activation.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to Ko and De Lacharriere have been addressed above. The examiner has not implied that applicant admits that cremophor EL causes complement activation. However, the references cited on pages 5 and 6 are suggestive of cremophor EL causing hypersensitive reactions. The reference of Michaud especially appears to teach on page 1402 (col.2) cremophor EL causes hypersensitivity reactions though on rare occasions. Whether rare or not, if cremophor EL causes hypersensitive reactions, one of ordinary skill in the art would be motivated to include an inhibitor in the compositions containing cremophor to avoid such reactions based on the combined teachings of Ko and De Lacharriere. Applicant's arguments thus, are not found to be persuasive.

1. This is a 1.114 continuation of applicant's earlier Application No. 09/183,375. All claims are drawn to the same invention claimed in the earlier application and could have

been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is 703 308 2440. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703 308 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308

1234.



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK